Further with regard to the foregoing, and with regard specifically to the §112 rejection raised in cipher 5(B) of the Action, a brief review of the state-of-the art and the invention may be helpful to the Examiner.

Chicory conventionally has been cultivated primarily in certain northern regions of Western Europe, where the chicory is seeded in Spring (typically from about mid-April to end-April) and the roots are harvested late Autumn, from about mid- or end-September to about end-November (as indicated in the Description p. 8, line 20 to p. 9, line 7). In the concerned regions, typically Belgium, frost commonly occurs from the end of October onwards (though the frost is not permanent).

Chicory traditionally is grown for the cultivation of Belgian endive (after harvesting late Autumn and cold storage, the roots are again planted and forced at about 15°C in the dark to yield white sprouts, known as Belgian endive), and for the manufacture of coffee substitute (i.e., roasted chicory roots in shredded form).

In recent years, chicory roots have also been grown for the manufacture of inulin, a reserve carbohydrate stored in the chicory roots. The inulin is isolated from the roots by conventional processes, typically by hot water extraction of the shredded roots, followed by conventional purification processes including liming, carbonation and filtration to remove thus precipitated impurities, followed by desalting of the filtrate via ion-exchangers, treatment with active carbon, and conventional isolation of the inulin from the obtained purified and clarified aqueous filtrate. Said chicory inulin is a polydisperse mixture of carbohydrates typically containing monomeric saccharides (glucose an fructose), the dimeric saccharide sucrose, and

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inulin, comprising fructo-oligosaccharides with a degree of polymerization (DP) < 10, and fructo-polysaccharides of DP 10 to about 70.

For producing chicory roots for the manufacture of inulin, the conventional seeding, growing and harvesting periods have been used. Furthermore, the harvested chicory roots are conventionally processed into inulin as soon as possible after harvesting, since the DP of the inulin molecules is known to decrease with increasing storage time of the roots (conventionally cool storage, protected from frost).

Various grades of inulin are known that are obtained by particular treatments, involving conventional techniques, of native or standard grade inulin, for example, low-sugar grade inulin (inulin from which monomeric and dimeric saccharides have been removed, e.g., by chromatographic treatment (as disclosed e.g. by Van Loo et al. in U.S. 5,660,872, derived from WO94/12541)), and high performance chicory inulin (long-chain chicory inulin prepared e.g. by fractionation via a directed crystallization from native or standard grade inulin (as disclosed by Smits et al. in U.S. 6,303,778, derived from WO96/01849)), as indicated in the subject Patent Application (p. 5, line 24 to p. 7, line 36).

Such extraction, purification and fractionation techniques applied to chicory roots and to inulin are known (p. 3, line 32 to p. 7, line 36). However, these aspects of the manufacture of inulin and of various grades of inulin are not the essential part of the process according to the present invention. Indeed, what is essential for the process for the manufacture of chicory inulin according to the present invention, is the improvement over conventional processes that the chicory roots that are used in the process of the present invention are non-conventionally cultivated, harvested and processed. By non-conventionally cultivated, harvested and processed

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is meant cultivated, harvested and processed in such a manner that the period for obtaining and processing the chicory roots, namely the whole of the period embracing the seeding, growing, harvesting, storing and processing of the roots, does not correspond to the conventional period (what has been indicated/defined in the description and claims of the subject patent application by the term "that partially or wholly falls outside conventional seeding, growing and processing periods").

In other words, there may be, at most, only a partial overlap of the period (taken as a whole) for obtaining (seeding and growing), harvesting and processing of the chicory roots, with the conventional period (defined on p. 8, lines 20-25 of the description). This is reflected in the claims. For example, in claim 65, the chicory roots used as source material in the process of the present invention, have to comply with particular requirements with respect to seeding time and minimum growing period, as well as to minimum length of the period (growing period + harvesting + processing period) during which no low temperature conditions occur that trigger the FEH gene in the roots. The latter period is defined as "from the beginning of the third month of the growing period till the end of the processing" and, for the chicory seeded in the northern hemisphere from March 15 till May 14, as " a period of at least 220 consecutive days immediately preceding the processing of the roots". Furthermore, the particular seeding periods in combination with the required length of the corresponding growing periods, constitute a further specific and particular requirement for the roots.

Accordingly, the period (taken as a whole) for obtaining and harvesting/processing the chicory roots used in the process of the present invention is well delimited and clearly different from the conventional period (taken as a whole).

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Thus, it is submitted that the term "partially or wholly falls outside conventional ones [periods]" is clear in view of the explanation given above, as well as in view of the corresponding definitions and explanations given already in the description.

Furthermore, from the description p.8, line 20 to p.9, line 7, directly follows that the term "conventional period" (embracing seeding, growing and processing (=harvesting +possible storage + processing (see p.3, lines 4-16)) includes the occurrence of low temperature conditions (frost), typically at the end of the growing period and/or during the harvesting period (from end October onwards), that trigger the FEH gene. Indeed, as already indicated above, in the northern part of Western Europe where chicory roots are conventionally cultivated and harvested late Autumn, frost commonly occurs from about end October (although not continuously, but nevertheless sufficiently enough to trigger the FEH gene, as evidenced by the observed decrease in DP of the inulin and increase of fructose in chicory roots from about end October onwards; see Van Den Ende et al., o.c., e.g., p. 47, col. 2 §1 (end) and Fig. 4, and p. 48, col. 2 §3).

In contrast with the conventional conditions for cultivating chicory roots, the occurrence of low temperature conditions (frost) with triggering of the FEH gene during a well defined period of the cultivation, harvesting and processing of chicory roots for the process according to the present invention, is explicitly excluded, as follows from the terms of claim 65.

As the Examiner is well aware, Applicants are permitted to be their own lexographers. In this case, the claims are clear and succinct. No terms in the claims are being used in a manner inconsistent with the specification or with generally accepted usage in the art.

Moreover, defining claims in terms of growing season is an acceptable method of claiming, as exemplified, for example, by prior U.S. Patent Nos. 4,511,561; 5,331,908 and

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5,141,552 (copies enclosed), which are given as exemplary. Actually, there are many U.S. patents defining manufacturing process in terms of growing season.

Accordingly, in view of the foregoing amendments and comments, it is submitted that the claims satisfy the requirements of 35 USC §112.

Turning to the art rejections, and considering first the rejection of claims 65-78 and 89-97 as obvious from Yamazaki et al. (U.S. Patent No. 4,613,377) in view of Van Den Ende et al. (Plant Physiol. Vol. 149: 43-50, 1996), the primary reference Yamazaki et al. discloses a process for the manufacture of a syrup of fructose or of fructose and [polydisperse] oligofructose from an aqueous inulin solution, by respectively a complete hydrolysis or a partial hydrolysis of the inulin.

The aqueous inulin solution is obtained from tubers of Jerusalem artichoke or from chicory roots by extraction with hot water according to a merely conventional process (Yamazaki, col. 10, line 57 to col. 11, line 4). Furthermore, Applicants emphasize that Yamazaki et al. only discloses conventional cultivation of J. artichoke tubers and chicory roots, including harvesting late October (col. 12, lines 22-27).

The process for obtaining (the aqueous solution of) inulin, including the source chicory roots, disclosed in Yamazaki et al. is thus completely conventional.

Yamazaki et al. is completely silent regarding the possibility of cultivating chicory roots for the manufacture of inulin in periods that do not correspond to the conventional ones.

Yamazaki et al. does not contain any teaching about the possibility or need of cultivating and/or using such source chicory roots for the manufacture of inulin.

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Applicants submit that the conventional cultivation of chicory roots, including seeding, growing and harvesting/processing, is clearly excluded from the scope of claim 65. The terms of the claim indeed define through the combination of all the indicated features a particular requirement (to be seen as a whole) that clearly is not fulfilled by the conventional cultivation of chicory roots.

The subject invention clearly resides in particular source material for the process for the manufacture of inulin, which source material has to fulfill particular requirements resulting from the combination of particular seeding periods, particular lengths of period of grow, of lengths of periods of harvesting /processing, and particular requirements for temperature conditions during certain, well defined periods of growth and harvesting/processing.

The use of said particular source material in the process according to the present invention clearly results in considerable technical advantages, including, for example, improved grades of inulin (Description p.13, lines 10-20 and p.16, lines 6-14) as well as in inter alia an extension of the possible growing period and growing season with subsequent technical benefits (e.g. Description, p.24, line 33 to p.25, line 24). Thus, Yamazaki et al. does not teach the claimed invention.

It is not seen that Van Den Ende et al. supplies the teachings to Yamazaki et al. to achieve or render obvious the claimed invention. In Van Den Ende et al., like Yamazaki et al., chicory roots are cultivated in the conventional manner. Indeed, on p.44, Col. 1, Materials and Methods, it is indicated that chicory was sown (in, e.g., Belgium) on June 1 and that on a weekly basis from July 26, plants were uprooted and the roots were investigated for fructan analysis/degrading till December 6th. This covers a total period of 189 days. However, as

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Van Den Ende et al. has had a growing period free of frost (and thus without triggering of the FEH gene of about 153 days, which is far below the at least 180 days stipulated in claim 65 for chicory sown in the Northern Hemisphere from June 1 till June 14. Subsequent cold storage at +1°C and forcing at 16°C of the roots, disclosed in Van Den Ende et al., is directly related to the production of Belgian endive and clearly falls outside the scope of the present invention.

Compared to the roots used in the process of the present invention, the chicory roots according to Van Den Ende et al. have had a too short growing period (from June 1 till end October), or when the growing period was longer (till December 6th), the roots were subjected to low temperature conditions that triggered FEH activity and resulted in significant degradation of inulin.

Accordingly, Van Den Ende et al. also does not disclose cultivation of chicory roots otherwise than in a conventional manner and in fact teaches away from non-conventional cultivation of chicory roots because it generically teaches that low temperature conditions should be avoided because they provoke degradation of inulin in chicory roots.

Van Den Ende et al. clearly only relates to conventional cultivation of chicory roots (for Belgian endive production) and does not disclose the possibility to grow chicory roots under other than conventional conditions. Van Den Ende et al. does not give any teaching or incentive at all to the skilled person to cultivate chicory roots (for the manufacture of inulin) otherwise than conventionally.

Accordingly, no combination of Yamazaki et al. and Van Den Ende et al. could achieve the claimed invention, and the skilled person would have no incentive in Yamazaki et al. in

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combination with Van Den Ende et al. to examine a possible substitution of chicory roots source material that has been conventionally cultivated by non-conventionally cultivated chicory roots source material. The possibility to obtain non-conventionally cultivated chicory roots source material was unknown and unexpected at the filing date of the subject patent application. Accordingly there was no teaching to the skilled person that said substitution was possible with a reasonable expectation of success. Therefore, the present invention is non-obvious in view of Yamazaki et al. in combination with Van Den Ende et al. Thus, the rejection of claims 65-78 and 89-97 as obvious from Yamazaki et al. in view of Van Den Ende et al. is in error.

Turning to the rejection of claims 79-88 as obvious from Yamazaki et al. in view of Van Den Ende et al. and further in view of Van Loo et al. (U.S. Patent No. 5,660,872), claims 79-88 are all directly or indirectly dependent on claim 65. The deficiencies of the combination of Yamazaki et al. and Van Den Ende et al. vis-à-vis claim 65 are discussed above. It is not seen that Van Loo et al. supplies the missing teachings to Yamazaki et al. and Van Den Ende et al. to achieve or render obvious claim 65 or any of the claims dependent thereon.

Van Loo et al. merely relates to a process for the manufacture of a particular grade of inulin, namely inulin that is free from mono-and disaccharides, by a chromatographic separation of a polydisperse inulin obtained by extraction from e.g. chicory roots (col. 6, lines 50-63). The inulin is apparently obtained from chicory roots through a conventional process and no particulars or requirements being disclosed about the chicory roots, these roots apparently have also been obtained conventionally.

Applicants emphasize that the disclosure of Van Loo et al. in fact only relates to a separation / fractionation process starting from inulin and that no disclosures nor any teaching at

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all is present in Van Loo et al. leading the skilled person to the present invention or giving an incentive to examine the cultivation of chicory roots under non-conventional conditions for use as a source material for the manufacture of inulin.

As is clearly indicated in the description of the present invention, the essential of the invention does not consist in a process of extracting, purifying or fractionating inulin as explicitly stated by the terms of claim 65 reading "In a process for the manufacture of chicory inulin from chicory roots through conventional manufacturing techniques," but in the improvement that resides in the use of new and non-obvious source material for said manufacture, namely chicory roots that are non-conventionally cultivated and harvested/processed as stipulated in claim 65.

Accordingly, Yamazaki at al. in combination with Van Den Ende et al., or Yamazaki et al. in combination with Van den Ende et al. and Van Loo et al., does not teach or suggest the possibility to cultivate chicory roots (including seeding, growing, harvesting/processing) according to the present invention, nor provides an incentive to the skilled person to even consider said possibility, and to use these chicory roots as source material for the manufacture of inulin.

Neither the combination of any two of the three cited documents, not the combination of all three prior art documents provide sufficient information – in fact any information at all – to lead the skilled person to the present invention.

Furthermore, low temperature conditions are taught by Van Den Ende et al. to be unfavorable for the synthesis of inulin, particularly inulin with a moderate to high degree of polymerisation. Thus, Van Den Ende et al. teaches <u>against</u> the claimed invention. Besides, from

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Van Den Ende et al. it could not be derived at all that such low temperature conditions that trigger the FEH gene, and thus trigger inulin degrading activity in the roots, may well occur during a certain early period in the cultivation process. Neither could it be derived from Yamazaki et al. in combination with Van Den Ende et al. and/or Van Loo et al. that, when said low temperature conditions had occurred (and the FEH gene was thus triggered) in an early stage of the growing period, the FEH activity would not continue for the whole of the growing period and thus provoke in a continuous manner the degradation of inulin in the chicory roots. This phenomenon is what surprisingly has been found by the inventors and has lead to the subject invention.

Accordingly, in the absence of any teaching about the possibility of non-conventional cultivation of chicory roots for inulin production according to the present invention and in the absence of any incentive for the skilled person from Yamazaki et al. in combination with Van Den Ende et al. and/or Van Loo et al. to examine the possibility of such cultivation of chicory roots for inulin production, the subject invention is clearly non-obvious.

It is therefore submitted that the rejection of claims 79-88 as obvious from Yamazaki et al. in view of Van Den Ende et al. and further in view of Van Loo et al. also is in error.

Having dealt with all the objections previously raised by the Examiner, the Application is believed to be in order for allowance. Early and favorable action are respectfully requested.

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In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account No. 08-1391.

Respectfully submitted,

Norman P. Soloway Attorney for Applicants Reg. No. 24,315

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## MARKED COPY OF AMENDED CLAIM

SERIAL NO. 09/600,732

**DOCKET: TIENSE RAFF.26** 



Serial No. 09/600,732 Docket No. Tiense Raff.26 Marked Claims - Amendment D

## MARKED CLAIMS SHOWING CHANGES MADE:

- 65. (Amended) In a process for the manufacture of chicory inulin from chicory roots through conventional manufacturing techniques, the improvement wherein:
- the source material for the process are roots of chicory which have been grown in appropriate regions and have been seeded, grown and[/or] processed in a period that partially or wholly falls outside conventional seeding, growing and[/or] processing periods, and which have been grown and processed under proper climatological temperature conditions which are such that during a period of at least from the beginning of the third month of the growing period till the end of the processing of the chicory roots the fructan exohydrolase (FEH) gene in the chicory roots has not been triggered by the occurrence of low temperature conditions,
- said chicory roots have had a growing period of at least 150 days,
- said chicory has been seeded
- in the northern hemisphere within a period selected from the periods ranging from December 1 till March 14, from March 15 till May 14, from May 15 till May 31, from June 1 till June 14, and from June 15 till November 30, provided that when said chicory has been seeded in the periods from May 15 till May 31, and from June 1 till June 14, the chicory roots have had a growing period of at least 180 days, and provided that when said chicory has been seeded in the period from March 15 till May 14, the chicory roots have been grown and processed under climatological conditions wherein, within a period of at least 220 consecutive days immediately preceding the end of the processing of the roots, no low temperature

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conditions occurred which triggered the FEH gene, and the chicory roots have had a minimum growing period of at least 160 days,

in the southern hemisphere within a period selected from the periods ranging from June 1 till September 14, from September 15 till September 30, from October 1 till November 14, from November 15 till November 30, and from December 1 till May 31.